PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Colloca, *et al.*	
Serial No.:	10/587,389 - Case No.: ITR0048YP	Art Unit:
Filed:	July 24, 2006	Examiner:
For:	CHIMPANZEE ADENOVIRUS VACCINE CARRIERS	

RECEIVED

FEB 02 2009

PCT LEGAL ADMINISTRATION

Mail Stop PCT
Commissioner for Patents
Office of PCT Legal Administration
P.O. Box 1450
Alexandria, VA 22313-1450

<u>**PETITION TO CORRECT DISCREPANCY IN FILING DATE OF**</u>
<u>**US NATIONAL PHASE APPLICATION UNDER 37 C.F.R. § 1.10(c)**</u>

Sir:

1. Pursuant to 37 C.F.R. § 1.10(c), this is a petition to correct the filing date of the above-referenced application, which is a §371 of PCT/EP2005/000558, international filing date of January 18, 2005, based on a discrepancy between the "date-in" specified on the "Express Mail" mailing label and the filing date accorded by the Office.

2. On January 18, 2005, Applicants filed international application PCT/EP2005/000558, which designated the United States and claimed priority to U.S. Provisional Application No. 60/538,799, filed January 23, 2004. A copy of the international application was communicated to the Office from the International Bureau on August 4, 2005.

3. The thirty-month period for paying the basic national fee in the United States expired at midnight on July 24, 2006 (July 23, 2006 being a Sunday).

4. On July 24, 2006, the following documents were filed by Applicants using the "Express Mail Post Office to Addressee" service of the U.S. Postal Service (USPS): (1) Transmittal Letter to the US Designated/Elected Office Concerning a Filing under 35 U.S.C. §371; (2) Declaration and Power of Attorney for Utility or Design Patent Application (37 C.F.R. 1.63); (3) a Sequence Requirement Statement; (4) a diskette containing the Sequence Listing in computer readable form; (5) an Information Disclosure Statement under 37 C.F.R. 1.97 and copies of corresponding references; and (6) a postcard listing the above documents.

5. The above-referenced transmittal letter filed by Applicants included an authorization to charge Deposit Account 13-2755 in the amount of $3,900 to cover the National Phase filing fees. The transmittal letter further included an authorization by Applicants to charge any additional fees which may be required, or credit any overpayment, to Deposit Account 13-2755.

6. The transmittal letter filed by Applicants included an Express Mail Certificate certifying that the correspondence was being deposited with the US Postal Service as Express Mail "Post Office to Addressee" on July 24, 2006 in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. The Express Mail Certificate listed Express Mail No. EV321988999US and was signed by Ms. Linda Zehrer and dated July 24, 2006.

7. The postcard listing documents mailed to the Office on July 24, 2006 indicated the Express Mail number EV321988999US. It was date-stamped by the PCT/USPTO with a date of July 25, 2006 and returned to Applicants.

8. On April 14, 2008, Applicants mailed a REQUEST FOR STATUS to the Office indicating that six months or more had passed since the application was filed on July 24, 2006 and requesting that the Office insert the status information and return the letter to Applicants. A postcard listing the Status Inquiry was mailed with the document and date-stamped April 17, 2008 by the Office, indicating that the PTO acknowledged receipt of the Status Inquiry on that date. The REQUEST FOR STATUS and postcard are attached herein as "Exhibit A".

9. On July 10, 2008, a NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 (Form PCT/DO/EO/905) ("Notification") was mailed by the Office indicating, *inter alia*, that an oath or declaration in compliance with 37 C.F.R. 1.497(a)-(b) was required. A copy of the Notification is attached herein as "Exhibit B."

10. A response to the Notification was mailed by Applicants on September 10, 2008. The response included, *inter alia*, a Preliminary Amendment, a Declaration and Power of Attorney, an authorization to charge Deposit Account 13-2755 for the surcharge required by 37 C.F.R. 1.492(h), and an authorization to charge any fees associated with the submission of the response to Deposit Account 13-2755. A copy of the response to the Notification (minus attachments) is attached herein as "Exhibit C."

11. A Notification of Abandonment ("Abandonment Letter") was mailed by the Office of PCT Legal Affairs on December 31, 2008 and received by the Applicants on January 5, 2009. A copy of the Abandonment Letter is attached herein as "Exhibit D." The Abandonment Letter states, *inter alia*, that the above-identified application was abandoned as of midnight 24 July 2006 for failure to pay the full basic national fee by thirty months from the priority date. The Abandonment Letter further states that the NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371, mailed 10 July 2008, is vacated.

12. Attached to this petition is a Declaration of Ms. Linda Zehrer and accompanying exhibits. Ms. Zehrer is employed in Applicants' Legal Administration Department. At the time of filing Application 10/587,389, her job responsibilities included receiving patent correspondence from attorneys to be filed by the "Express Mail Post Office to Addressee" service of the USPS and depositing said correspondence directly with an employee of the USPS. The attached declaration indicates that Ms. Zehrer deposited the documents specified in paragraph (4) above directly with an employee of the USPS on July 24, 2006.

13. Attached to Ms. Zehrer's declaration as "Exhibit D-1" is a copy of the Express mail receipt for Express Mail number EV321988999US indicating that the documents

specified in paragraph (4) above were deposited with the USPS on July 24, 2006. Also attached to Ms. Zehrer's Declaration is a copy of the Transmittal Letter referenced in paragraph (4) above. The Transmittal Letter contains an Express Mail Certificate for Express Mail No. EV321988999US that certifies that Ms. Zehrer received the correspondence and deposited it with the USPS as Express Mail "Post Office to Addressee" on July 24, 2006, in an envelope marked Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

14. Based on the discrepancy noted above between the "date-in" of July 24, 2006 specified on the "Express Mail" mailing label and the filing date of July 25, 2006 accorded by the Office, Applicants respectfully request that the USPTO correct the filing date of the above-referenced application in accordance with the submitted evidence. Specifically, Applicants request that the Office amend the filing date of the above-referenced application to indicate that it was timely filed on July 24, 2006.

15. Any fees required in connection with this Petition may be charged to Merck Deposit Account No. 13-2755. The examiner is invited to contact the undersigned attorney at the telephone number provided below if such would advance the prosecution of the case.

Respectfully submitted,

By _____
Alysia A. Finnegan
Reg. No.: 48,878
Attorney for Applicants

MERCK & CO., INC.
P.O. Box 2000
Rahway, NJ 07065-0907
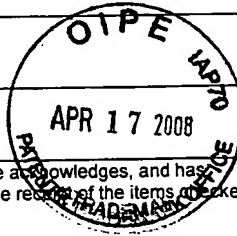(732) 594-2583

Date: January 29, 2009

Exhibit A

Request for Status

EXHIBIT A

P&T OFFICE ACKNOWLEDGEMENT

ATTORNEY	DATE
Alysia A. Finnegan	4/14/2008

CASE NUMBER/	SERIAL NUMBER
ITR0048YP	10/587,389

DATE FILED

July 24, 2006

APPLICANT

Colloca et al.

EXPRESS MAIL NO.

APR 17 2008

OIPE

The Patent & Trademark Office acknowledges, and has
stamped hereon, the date of the receipt of the items checked
below:

☐ AMENDMENT

☐ APPEAL AND FEE

☐ BRIEF

☐ CERTIFICATE OF CORRECTION

☐ FINAL FEE

☒ LETTER Status Inquiry

☐ INFORMATION DISCLOSURE STATEMENT

☐ PTO 1449 & REFERENCES

☐ PETITION FOR EXTENSION OF TIME & FEE

☐ INVITATION TO CORRECT

☐ DEMAND-CHAPTER II & FEE SHEET

☐ SEQUENCE STATEMENT

☐ SEQUENCE LISTING

☐ SEQUENCE DISKETTE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Colloca et al.

Serial No.: 10/587,389

Filed: July 24, 2006

For: CHIMPANZEE ADENOVIRUS VACCINE CARRIERS

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR STATUS

Sir:

In the matter of the above-identified application, six months or more have passed since

the application was filed on July 24, 2006.

Applicant(s) request(s) that the Patent and Trademark Office insert below the status information requested

and return this letter. A duplicate copy of this letter is enclosed for the Patent and Trademark Office records.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Jodi Hobbs Date 4/14/2008

Respectfully submitted,

By: Alysia A. Finnegan
Attorney for Applicant(s)

Reg. No. 48,878

MERCK & CO., INC.
Patent Department, RY60-30
P.O. Box 2000
Rahway, N.J. 07065-0907
(732)594-2583

DATE: April 14, 2008

1. This application is (still pending _____).

(abandoned _____).

2. Official Action on this application can be expected on or about _____ ; or

3. Official Action on this application was mailed on _____ .

(In Duplicate)

Exhibit B

Notification of Missing Requirements
Under 35 U.S.C. 371

EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/587,389	Stefano COLLOCA	ITR0048YP

210
MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

INTERNATIONAL APPLICATION NO.	
PCT/EP05/00558	
I.A. FILING DATE	PRIORITY DATE
01/18/2005	01/23/2004

CONFIRMATION NO. 4904
371 FORMALITIES LETTER

OC000000030803064

Date Mailed: 07/10/2008

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371
IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- Priority Document
- Copy of the International Application filed on 07/25/2006
- Copy of the International Search Report filed on 07/25/2006
- Information Disclosure Statements filed on 07/25/2006
- Biochemical Sequence Diskette filed on 07/25/2006
- Oath or Declaration filed on 07/25/2006
- Biochemical Sequence Listing filed on 07/25/2006
- U.S. Basic National Fees filed on 07/25/2006
- Priority Documents filed on 07/25/2006
- Specification filed on 07/25/2006
- Claims filed on 07/25/2006
- Abstracts filed on 07/25/2006
- Drawings filed on 07/25/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of **$520** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - not executed by inventor Sporeno
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is $650 for a Large Entity:

page 1 of 2

FORM PCT/DO/EO/905 (371 Formalities Notice)

- **$130** Surcharge.
- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). Refer to attachment or PAIR document dated see report dated 08/09/06.

Total additional claim fee(s) for this application is **$520**
- **$150** for **25** total claims over 20.
- **$370** for multiple dependent claim surcharge.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov**

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

FRANCINE YOUNG

Telephone: (703) 308-9140 EXT 215

page 2 of 2

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING
ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information
Center (STIC) detected errors when processing the following computer readable
form:

Application Serial Number: _10/587,389_
Source: _1Fwp_
Date Processed by STIC: _8/9/06_

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE
    APPLICANT, WITH A NOTICE TO COMPLY or,
2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A
    NOTICE TO COMPLY
FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT
MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO **REDUCE** ERRORED SEQUENCE LISTINGS, **PLEASE** USE THE **CHECKER
VERSION 4.4.0 PROGRAM**, ACCESSIBLE THROUGH THE U.S. PATENT AND
TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:
        http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is
a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.
Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.
Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the
United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio **(<http://www.uspto.gov/ebc/efs/downloads/documents.htm>** , **EFS Submission
   User Manual** - ePAVE)
2. **U.S. Postal Service:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. **Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):**
   U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street,
   Alexandria, VA 22314

Revised 01/10/06

Raw Sequence Listing Error Summary

ERROR DETECTED	SUGGESTED CORRECTION	SERIAL NUMBER: *10/587,389*

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1____Wrapped Nucleics
Wrapped Aminos — The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."

2____Invalid Line Length — The rules require that a line not exceed 72 characters in length. This includes white spaces.

3____Misaligned Amino Numbering — The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.

4 *i)*___Non-ASCII — The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.

5____Variable Length — Sequence(s)____contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.

6____PatentIn 2.0
"bug" — A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) _____. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. **This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.**

7____Skipped Sequences (OLD RULES) — Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
(i)   SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)
(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
This sequence is intentionally skipped
Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.

8____Skipped Sequences (NEW RULES) — Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence.
<210> sequence id number
<400> sequence id number
000

9____Use of n's or Xaa's (NEW RULES) — Use of n's and/or Xaa's have been detected in the Sequence Listing.
Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.

10____Invalid <213> Response — Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence. (see item 11 below)

11____Use of <220> — Sequence(s) ___ missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section or use "chemically synthesized" as explanation. (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32), also Sec. 1.823 of Sequence Rules

12____PatentIn 2.0
"bug" — Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.

13____Misuse of n/Xaa — "n" can only represent a single nucleotide; "Xaa" can only represent a single amino acid

AMC – STIC Systems Branch – 03/02/06

IFWP

RAW SEQUENCE LISTING
PATENT APPLICATION: US/10/587,389

DATE: 08/09/2006
TIME: 10:06:36

Input Set : N:\SSLM\10587389.txt
Output Set: N:\CRF4\08092006\J587389.raw

```
      4 <110> APPLICANT: Stefano Colloca
      5         Alfredo Nicosio
      6         Elisabetta Sproreno
      7         Agostino Cirillo
      8         Bruno Bruni Ercole
      9         Annalisa Meola
     11 <120> TITLE OF INVENTION: CHIMPANZEE ADENOVIRUS VACCINE CARRIERS
     14 <130> FILE REFERENCE: ITR0048YP
C--> 16 <140> CURRENT APPLICATION NUMBER: US/10/587,389
C--> 16 <141> CURRENT FILING DATE: 2006-07-25
     16 <150> PRIOR APPLICATION NUMBER: 60/538,799
     17 <151> PRIOR FILING DATE: 2004-01-23
     19 <150> PRIOR APPLICATION NUMBER: PCT/EP2005/000558
     20 <151> PRIOR FILING DATE: 2004-01-18
     22 <160> NUMBER OF SEQ ID NOS: 125
     24 <170> SOFTWARE: FastSEQ for Windows Version 4.0
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see item 4 on Err. Summary sheet

see pp. 2, 4-6, 9-12, 14,15, 17-18

Does Not Comply
Corrected Diskette Needed

ERRORED SEQUENCES

```
   1294 <210> SEQ ID NO: 3
   1295 <211> LENGTH: 36606
   1296 <212> TYPE: DNA
   1297 <213> ORGANISM: Chimpanzee Pan 6 (CV32) Genomic
   1299 <400> SEQUENCE: 3
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   1301 atttggggag ggaggaaggt gattggctgc gggagcggcg accgttaggg gcggggcggg 120
   1302 tgacgttttg atgacgtggc tatgaggcgg agccggtttg caagttctcg tgggaaaagt 180
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     1330 ggccatcagt ctcactttaa ccagagtatt ctgagagccc ttgactttc tactcctggc 1860
     1331 agaactaccg ccgcggtagc ctttttttgcc tttattcttg acaaatggag tcaagaaacc 1920
     1332 catttcagca gggattaccg tctggactgc ttagcagtag ctttgtggag aacatggagg 1980
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     1338 ctgtcagtct gatgagccgc aggcgcccag aatcggtgtg gtggcatgag gtgcagtcgc 2340
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p. 18

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10540 Gly Gln Asp Ala Ser Glu Tyr Leu Ser Pro Gly Leu Val Gln Phe Ala
10541             20                  25                  30
10542 Arg Ala Thr Asp Thr Tyr Phe Ser Leu Gly Asn Lys Phe Arg Asn Pro
10543         35                  40                  45
10544 Thr Val Ala Pro Thr His Asp Val Thr Thr Asp Arg Ser Gln Arg Leu
10545     50                  55                  60
10546 Thr Leu Arg Phe Val Pro Val Asp Arg Glu Asp Asn Thr Tyr Ser Tyr
10547 65                  70                  75                  80
10548 Lys Val Arg Tyr Thr Leu Ala Val Gly Asp Asn Arg Val Leu Asp Met
10549                 85                  90                  95
10550 Ala Ser Thr Tyr Phe Asp Ile Arg Gly Val Leu Asp Arg Gly Pro Ser
10551             100                 105                 110
10552 Phe Lys Pro Tyr Ser Gly Thr Ala Tyr Asn Ser Leu Ala Pro Lys Gly
10553         115                 120                 125
10554 Ala Pro Asn Thr Cys Gln Trp Thr Tyr Lys Ala Asp Gly Glu Thr Ala
10555     130                 135                 140
10556 Thr Glu Lys Thr Tyr Thr Tyr Gly Asn Ala Pro Val Gln Gly Ile Asn
10557 145                 150                 155                 160
10558 Ile Thr Lys Asp Gly Ile Gln Leu Gly Thr Asp Thr Asp Asp Gln Pro
10559                 165                 170                 175
10560 Ile Tyr Ala Asp Lys Thr Tyr Gln Pro Glu Pro Gln Val Gly Asp Ala
10561             180                 185                 190
10562 Glu Trp His Asp Ile Thr Gly Thr Asp Glu Lys Tyr Gly Gly Arg Ala
10563         195                 200                 205
10564 Leu Lys Pro Asp Thr Lys Met Lys Pro Cys Tyr Gly Ser Phe Ala Lys
10565     210                 215                 220
10566 Pro Thr Asn Lys Glu Gly Gly Gln Ala Asn Val Lys Thr Gly Thr Gly
10567 225                 230                 235                 240
10568 Thr Thr Lys Glu Tyr Asp Ile Asp Met Ala Phe Phe Asp Asn Arg Ser
10569                 245                 250                 255
10570 Ala Ala Ala Ala Gly Leu Ala Pro Glu Ile Val Leu Tyr Thr Glu Asn
10571             260                 265                 270
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10572 Val Asp Leu Glu Thr Pro Asp Thr His Ile Val Tyr Lys Ala Gly Thr
10573         275             280             285
10574 Asp Asp Ser Ser Ser Ser Ile Asn Leu Gly Gln Gln Ala Met Pro Asn
10575         290             295             300
10576 Arg Pro Asn Tyr Ile Gly Phe Arg Asp Asn Phe Ile Gly Leu Met Tyr
10577 305             310             315             320
10578 Tyr Asn Ser Thr Gly Asn Met Gly Val Leu Ala Gly Gln Ala Ser Gln
10579             325             330             335
10580 Leu Asn Ala Val Val Asp Leu Gln Asp Arg Asn Thr Glu Leu Ser Tyr
10581         340             345             350
10582 Gln Leu Leu Leu Asp Ser Leu Gly Asp Arg Thr Arg Tyr Phe Ser Met
10583         355             360             365
10584 Trp Asn Gln Ala Val Asp Ser Tyr Asp Pro Asp Val Arg Ile Ile Glu
10585         370             375             380
10586 Asn His Gly Val Glu Asp Glu Leu Pro Asn Tyr Cys Phe Pro Leu Asp
10587 385             390             395             400
10588 Ala Val Gly Arg Thr Asp Thr Tyr Gln Gly Ile Lys Ala Asn Gly Thr
10589             405             410             415
10590 Asp Gln Thr Thr Trp Thr Lys Asp Asp Ser Val Asn Asp Ala Asn Glu
10591         420             425             430
10592 Ile Gly Lys Gly Asn Pro Phe Ala Met Glu Ile Asn Ile Gln Ala Asn
10593         435             440             445
10594 Leu Trp Arg Asn Phe Leu Tyr Ala Asn Val Ala Leu Tyr Leu Pro Asp
10595         450             455             460
10596 Ser Tyr Lys Tyr Thr Pro Ala Asn Val Thr Leu Pro Thr Asn Thr Asn
10597 465             470             475             480
10598 Thr Tyr Asp Tyr Met Asn Gly Arg Val Val Ala Pro Ser Leu Val Asp
10599             485             490             495
10600 Ser Tyr Ile Asn Ile Gly Ala Arg Trp Ser Leu Asp Pro Met Asp Asn
10601         500             505             510
10602 Val Asn Pro Phe Asn His His Arg Asn Ala Gly Leu Arg Tyr Arg Ser
10603         515             520             525
10604 Met Leu Leu Gly Asn Gly Arg Tyr Val Pro Phe His Ile Gln Val Pro
10605         530             535             540
10606 Gln Lys Phe Phe Ala Ile Lys Ser Leu Leu Leu Leu Pro Gly Ser Tyr
10607 545             550             555             560
10608 Thr Tyr Glu Trp Asn Phe Arg Lys Asp Val Asn Met Ile Leu Gln Ser
10609             565             570             575
10610 Ser Leu Gly Asn Asp Leu Arg Thr Asp Gly Ala Ser Ile Ser Phe Thr
10611         580             585             590
10612 Ser Ile Asn Leu Tyr Ala Thr Phe Phe Pro Met Ala His Asn Thr Ala
10613         595             600             605
10614 Ser Thr Leu Glu Ala Met Leu Arg Asn Asp Thr Asn Asp Gln Ser Phe
10615         610             615             620
10616 Asn Asp Tyr Leu Ser Ala Ala Asn Met Leu Tyr Pro Ile Pro Ala Asn
10617 625             630             635             640
10618 Ala Thr Asn Val Pro Ile Ser Ile Pro Ser Arg Asn Trp Ala Ala Phe
10619             645             650             655
10620 Arg Gly Trp Ser Phe Thr Arg Leu Lys Thr Lys Glu Thr Pro Ser Leu
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      10621              660              665              670
      10622 Gly Ser Gly Phe Asp Pro Tyr Phe Val Tyr Ser Gly Ser Ile Pro Tyr
      10623          675              680              685
      10624 Leu Asp Gly Thr Phe Tyr Leu Asn His Thr Phe Lys Lys Val Ser Ile
      10625      690              695              700
      10626 Thr Phe Asp Ser Ser Val Ser Trp Pro Gly Asn Asp Arg Leu Leu Thr
      10627 705              710              715              720
      10628 Pro Asn Glu Phe Glu Ile Lys Arg Thr Val Asp Gly Glu Gly Tyr Asn
      10629              725              730              735
      10630 Val Ala Gln Cys Asn Met Thr Lys Asp Trp Phe Leu Val Gln Met Leu
      10631          740              745              750
      10632 Ala His Tyr Asn Ile Gly Tyr Gln Gly Phe Tyr Val Pro Glu Gly Tyr
      10633          755              760              765
      10634 Lys Asp Arg Met Tyr Ser Phe Phe Arg Asn Phe Gln Pro Met Ser Arg
      10635      770              775              780
      10636 Gln Val Val Asp Glu Val Asn Tyr Lys Asp Tyr Gln Ala Val Thr Leu
      10637 785              790              795              800
      10638 Ala Tyr Gln His Asn Asn Ser Gly Phe Val Gly Tyr Leu Ala Pro Thr
      10639              805              810              815
E--> 10640 Met Arg Gln Gly Gln Pro Tyr Pro Ala Xaa Tyr Pro Tyr Pro Leu Ile
      10641          820              825              830
      10642 Gly Lys Ser Ala Val Thr Ser Val Thr Gln Lys Lys Phe Leu Cys Asp
      10643          835              840              845
      10644 Arg Val Met Trp Arg Ile Pro Phe Ser Ser Asn Phe Met Ser Met Gly
      10645      850              855              860
      10646 Ala Leu Thr Asp Leu Gly Gln Asn Met Leu Tyr Ala Asn Ser Ala His
      10647 865              870              875              880
      10648 Ala Leu Asp Met Asn Phe Glu Val Asp Pro Met Asp Glu Ser Thr Leu
      10649              885              890              895
      10650 Leu Tyr Val Val Phe Glu Val Phe Asp Val Val Arg Val His Gln Pro
      10651          900              905              910
E--> 10652 His Arg Gly Val Ile Glu Ala Val Tyr Xaa Arg Thr Pro Phe Ser Ala
      10653          915              920              925
      10654 Gly Asn Ala Thr Thr
      10655      930
E--> 10658 - 1 -
```

delete

VARIABLE LOCATION SUMMARY   DATE: 08/09/2006
PATENT APPLICATION: US/10/587,389   TIME: 10:06:38

erra explanation

Input Set : N:\SSLM\10587389.txt
Output Set: N:\CRF4\08092006\J587389.raw

Use of n's or Xaa's(NEW RULES):
Use of n's and/or Xaa's have been detected in the Sequence Listing.
Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
in <220> to <223> section, please explain location of n or Xaa, and which
residue n or Xaa represents.

Seq#:3; N Pos. 3592,7705,11272,11275,15203,24396,27010,28655,30744,31045
Seq#:24; N Pos. 63
Seq#:125; Xaa Pos. 826,922

VERIFICATION SUMMARY
PATENT APPLICATION: US/10/587,389

DATE: 08/09/2006
TIME: 10:06:38

Input Set : **N:\SSLM\10587389.txt**
Output Set: **N:\CRF4\08092006\J587389.raw**

L:16 M:270 C: Current Application Number differs, Replaced Current Application No
L:16 M:271 C: Current Filing Date differs, Replaced Current Filing Date
L:1359 M:340 E: (46) "n" or "Xaa" used: Feature required, for SEQ ID#:3
M:340 Repeated in SeqNo=3
L:3859 M:340 E: (46) "n" or "Xaa" used: Feature required, for SEQ ID#:24
L:10640 M:340 E: (46) "n" or "Xaa" used: Feature required, for SEQ ID#:125
M:340 Repeated in SeqNo=125
L:10658 M:332 E: (32) Invalid/Missing Amino Acid Numbering, SEQ ID:125

Exhibit C

Response to Notification

EXHIBIT C   IAP04Rec'd PCT 15 SEP 2008

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Colloca *et al.*
Serial No.:	10/587,389 Case No.: ITR0048YP Art Unit:
Filing Date:	July 24, 2006
For:	CHIMPANZEE ADENOVIRUS VACCINE CARRIERS Examiner:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) AND PRELIMINARY AMENDMENT UNDER 37 C.F.R. §1.115

Sir:

This communication is in response to the outstanding Notification of Missing Requirements (copy attached), mailed July 10, 2008, in the above-identified application, having a two-month period for response set to expire September 10, 2008.

In response thereto, enclosed is a Declaration and Power of Attorney signed by all of the inventors except Elisabetta Sporeno, who is deceased. Applicants note that the Declaration was executed by Mr. Paolo Palozzolo, executor of the estate of Ms. Sporeno, on her behalf. Also enclosed is an authorization to charge Deposit Account No. 13-2755 for the surcharge required by 37 C.F.R. 1.492(h).

Applicants further enclose herewith a corrected Sequence Listing in compliance with 37 C.F.R. §§ 1.821 to 1.825, along with a corresponding Sequence Listing in computer readable form.

Any fees associated with the submission of this amendment and accompanying response to the Notice to File Missing Parts may be charged to Merck Deposit Account No. 13-2755.

AMENDMENTS TO THE SPECIFICATION appear on page 3 of this paper.

AMENDMENTS TO THE CLAIMS are reflected in the listing of claims which begins on page 3 of this paper

REMARKS begin on page 7 of this paper.

Please amend the application as follows:

IN THE SPECIFICATION:

Please delete the section titled "CROSS-REFERENCE TO RELATED APPLICATIONS", appearing on page 1, lines 4-6, and replace with the following new section:

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a §371 National Stage Application of PCT/EP2005/000558, international filing date of January 18, 2005, which claims the benefit of U.S. Provisional Application No. 60/538,799, filed January 23, 2004, now expired, herein incorporated by reference.

Please enter the corrected Sequence Listing provided herewith into the Specification.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Claim 1. (Currently Amended) ~~An isolated~~ A replication-defective chimpanzee vector which is at least partially deleted in E1 and devoid of E1 activity ~~nucleic acid sequence~~ comprising a sequence of nucleotides selected from the group consisting of:

a) SEQ ID NO: 1; and

b) SEQ ID NO: 2; ~~and~~

~~c) a nucleic acid sequence complementary to the sequence of (a) or (b)~~.

Claim 2. (Currently Amended) An isolated recombinant chimpanzee adenovirus serotype comprising a ~~any combination of hexon and fiber~~ nucleic acid sequence encoding a hexon protein, the nucleic acid sequence ~~sequences~~ selected from the group ~~groups~~ consisting of:

~~a) a hexon gene sequence selected from the group consisting of~~ SEQ ID NOS: 16-25, 41, 43, 97, 99, 101, 103, 105, 107, 109, 111, 113, 115, and 117. ~~; and~~

~~b) a fiber gene sequence selected from the group consisting of SEQ ID NOS: 6-15, 42, 44, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76 and 78.~~

Claim 3. (Currently Amended) An isolated recombinant chimpanzee adenovirus serotype comprising ~~any combination of hexon and fiber~~ a nucleic acid sequence encoding a fiber protein, the nucleic acid sequence ~~sequences derived from an adeonovirus~~ selected from the group consisting of: SEQ ID NOS: 6-15, 42, 44, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76 and 78. ~~isolates consisting of ECACC accession numbers 03121201 (ChAd4), 03121202 (ChAd5), 03121203 (ChAd7), 03121204 (ChAd9), 03121205 (ChAd10), 03121206 (ChAd11), 03121207 (ChAd16), 03121208 (ChAd17), 03121209 (ChAd19) and 03121210 (ChAd20)~~.

Claim 4. (Currently Amended) A replication defective chimpanzee adenoviral (ChAd) vector comprising a nucleotide sequence derived from an adeonovirus selected from the group of isolates consisting of ECACC accession numbers 03121201 (ChAd4), 03121202 (ChAd5), 03121203 (ChAd7), 03121204 (ChAd9), 03121205 (ChAd10), 03121206 (ChAd11), 03121207 (ChAd16), 03121208 (ChAd17), 03121209 (ChAd19) and 03121210 (ChAd20) and a transgene which encodes at least one immunogen operatively linked to regulatory sequences which direct expression of said transgene in mammalian cells, wherein said vector is at least partially deleted in E1 and devoid of E1 activity ~~lacks the nucleotide which~~

~~comprises at least one adenoviral gene selected from the group consisting of adenoviral E1, E2, E3, and E4~~.

Claim 5.   (Canceled)

Claim 6.   (Currently Amended)   ~~A~~ The replication defective ChAd vector of claim 1 which comprises a deletion/disruption in the E1 nucleotide sequence in the region from bp 460 to bp 3542 of SEQ ID NO: 1 or from bp 457 to bp 3425 of SEQ ID NO:2.

Claim 7.   (Canceled)

Claim 8.   (Currently Amended)   The replication-defective ChAd vector according to claim 6 wherein the vector further comprises ~~a deletion/disruption in the E1 nucleotide sequence in the region from bp 460 to bp 3542 of SEQ ID NO: 1 or from bp 457 to bp 3425 of SEQ ID NO: 2 and further wherein the vector comprises~~ a transgene encoding at least one tumor associated antigen (TAA) operatively linked to a promoter capable of directing expression of the transgene.

Claim 9-21.   (Canceled)

Claim 22.   (Currently Amended) A method of eliciting an immune response in a ~~naïve~~ mammal comprising administering to said mammal a sufficient amount of a the ChAd vector of claim 46 ~~which comprises a chimpanzee adenovirus genome containing at least a functional deletion of its E1 gene, a nucleotide encoding a target antigen and a promoter sequence capable of directing expression of the nucleotide sequence encoding the target antigen~~, wherein administration of the ChAd vector elicits a primary immune response.

Claim 23-29.   (Canceled)

Claim 30.   (Currently Amended)   The method of Claim ~~27~~ 22 wherein the immune response comprises the production of antigen-specific CD8+ T cells.

Claim 31-34.   (Canceled).

Claim 35.   (Currently Amended)   A method of breaking host tolerance to a self-antigen comprising:

(a) priming a host to respond to a self-antigen by administering a first vaccine composition comprising a nucleotide sequence encoding a self-antigen against which an antigen-specific immune response is desired, thereby eliciting a primed response; and

(b) boosting the primed immune response of step (a) by administering a second vaccine composition comprising a recombinant ChAd vector containing at least a functional deletion of its E1 gene, and in the site of the E1 gene deletion, a sequence comprising a promoter capable of directing expression of DNA encoding the same self-antigen delivered in the priming step, wherein administration of the boosting composition elicits an immune response which has the effect of breaking host tolerance to the self-antigen, wherein the ChAd vector is derived from an adenovirus selected from the group consisting of: ChAd3, ChAd6, ChAd20, ChAd4, ChAd5, ChAd7, ChAd9, ChAd10, ChAd11, ChAd16, ChAd17, ChAd19, ChAd8, ChAd22, ChAd24, ChAd26, ChAd30, ChAd31, ChAd37, ChAd38, ChAd44, ChAd63 and ChAd82.

Claim 36-41.   (Canceled)

Claim 42.   (Currently Amended)   The method of claim 35 wherein the first and second vaccine compositions are both comprise ChAd vectors characterized by different ChAd serotypes.

Claim 43.   (New)   A recombinant chimpanzee adenoviral (ChAd) vector which is at least partially deleted in E1 and devoid of E1 activity, wherein the adenoviral vector is derived from a chimpanzee adenovirus serotype selected from the group consisting of: ChAd3, ChAd6, ChAd20, ChAd4, ChAd5, ChAd7, ChAd9, ChAd10, ChAd11, ChAd16, ChAd17, ChAd19, ChAd8, ChAd22, ChAd24, ChAd26, ChAd30, ChAd31, ChAd37, ChAd38, ChAd44, ChAd63 and ChAd82.

Claim 44   (New)   An isolated host cell comprising the recombinant adenoviral vector of claim 43.

Claim 45   (New)   A method for producing recombinant, replication-defective chimpanzee adenovirus particles comprising:

(a) transfecting a recombinant adenoviral vector of claim 1 into a population of cells; and

(b) harvesting the resulting recombinant, replication-defective adenovirus.

Claim 46   (New)   The recombinant ChAd vector of claim 43, further comprising a heterologous nucleic acid which encodes at least one immunogen operatively linked to regulatory sequences which direct expression of said heterologous nucleic acid in mammalian cells.

Claim 47   (New)   The recombinant ChAd vector of claim 43, wherein the adenoviral vector is derived from ChAd3 or ChAd6.

Claim 48   (New)   The recombinant ChAd vector of claim 47, wherein the vector further comprises at least a partial deletion of nucleotide sequences which encode the adenovirus E3 protein.

Claim 49   (New)   The recombinant ChAd vector of claim 47, wherein the vector is completely deleted in E1.

Claim 50   (New)   The isolated host cell of claim 44, wherein the host cell is a 293 cell or a PER.C6™ cell.

REMARKS

Applicants respectfully request consideration of the application in view of the foregoing amendments and the following remarks.

The Specification has been amended to update status information for priority application 60/538,799 and to indicate that this application is a §371 National Stage Application of PCT/EP2005/000558.

Claims 5, 7, 9-21, 23-29, 31-34, and 36-41 are canceled herein without prejudice to pursuing the subject matter of said claims in a later filed divisional application(s).

Claim 1 is amended herein to claim a replication-defective chimpanzee adenovirus vector which is at least partially devoid of E1 and devoid of E1 activity. Support for the amendment can be found, *inter alia*, in the Specification on page 16, lines 9-24.

Claim 2 is amended herein to remove part (b) of the claim, which species fiber sequences, which are now described in amended claim 3. Support for the amendments to claims 2 and 3 can be found, *inter alia*, in original claim 2.

Claim 4 is amended herein to indicate that the replication defective ChAd vector is at least partially devoid of E1 and devoid of E1 activity. Support for the amendment can be found, *inter alia*, in the Specification on page 16, lines 9-24.

Claims 6, 22, and 30 are amended herein to change their dependencies.

Claim 8 is amended herein to indicate that the transgene is operatively linked to a promoter capable of directing its expression. Support for the amendment can be found, inter alia, in original claim 5.

Claim 22 is amended herein to depend from new claim 46.

Claim 35 is amended herein to specify the serotype of the adenovirus from which the ChAd vector is derived. Support for this amendment can be found, *inter alia*, in original claim 31.

New claims 42-50 are added. Support for the new claims can be found, *inter alia*, in original claims 1,5,16, and 17. No new matter has been added by the amendments herein.

Sequence Rules

In accordance with 37 CFR §§ 1.821 to 1.825, a substitute Sequence Listing and corresponding substitute computer readable form are provided herein to correct errors specified on the Notification of Missing Requirements. Specifically, the "n's" present in nucleotide sequences set forth in SEQ ID NOs: 3 and 24 have been defined as "n = A, T, C, or G." Further, the Xaa's present in SEQ ID NO:125 have been changed to Asn at position 826 and Leu at

position 922. The correct sequence for SEQ ID NO:125 was present in the priority application in Figure 31. Therefore, the correction to the Sequence Listing submitted herewith adds no new matter.

Oath or Declaration of the Inventors

In response to the Notification of Missing Requirements under 35 U.S.C. 371, provided herewith is a declaration of the inventors in compliance with 37 C.F.R. §1.497 (a) and (b). The declaration is signed by inventors Agostino Cirillo, Stefano Colloca, Bruno Bruni Ercole, Annalisa Meola, and Alfredo Nicosia. The declaration is also signed by Mr. Paolo Palozzolo, executor of the estate of deceased inventor Elizabeta Sporeno, on her behalf.
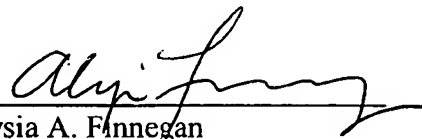
Summary

Applicants respectfully submit that all claims are in condition for allowance and a favorable action on the merits is earnestly solicited.

If the Examiner believes that a telephone conference would be of value, he is requested to call the undersigned attorney at the number listed below.

Respectfully submitted,

By _____

Alysia A. Finnegan
Reg. No. 48,878
Attorney for Applicant(s)

MERCK & CO., INC.
P.O. Box 2000
Rahway, New Jersey 07065-0907
(732) 594-2583

Date: September 10, 2008

Exhibit D

Notification of Abandonment

3 1 DEC 2008

MERCK AND CO., INC
P O BOX 2000
RAHWAY NJ 07065-0907

In re Application of	:
COLLOCA et al.	: NOTIFICATION
Application No.: 10/587,389	:
PCT No.: PCT/EP2005/000558	:
Int. Filing Date: 18 January 2005	:
Priority Date: 23 January 2004	:
Attorney's Docket No.: ITR0048YP	:
For: CHIMPANZEE ADENOVIRUS	:
VACCINE CARRIERS	:

This application is before the Office of PCT Legal Affairs for consideration of matters arising under 35 U.S.C. 371.

BACKGROUND

On 18 January 2005, applicants filed international application PCT/EP2005/000558, which designated the United States and claimed a priority date of 23 January 2004. A copy of the international application was communicated to the United States Patent and Trademark Office (USPTO) from the International Bureau on 04 August 2005. The thirty-month period for paying the basic national fee in the United States expired at midnight on 24 July 2006 (23 July 2006 being a Sunday).

A transmittal letter was filed by applicants for entry into the national stage in the United States which was accompanied by, *inter alia*, the basic national fee and a declaration of inventors. These papers were date-stamped 25 July 2006 by the USPTO.

On 10 July 2008, a NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 (Form PCT/DO/EO/905) was mailed indicating, *inter alia*, that an oath or declaration in compliance with 37 CFR 1.497(a)-(b) was required.

DISCUSSION

The above-identified application was abandoned as of midnight 24 July 2006 for failure to pay the full U.S. basic national fee by thirty months from the priority date. (USPTO records

show the payment as having been received 25 July 2006, one day late.) Accordingly, the NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 mailed 10 July 2008 is hereby <u>VACATED</u>.

The Transmittal Letter date-stamped 25 July 2006 includes a certification that the papers were mailed by Express mail on 24 July 2006. Accordingly, applicants may wish to consider filing a petition under 37 CFR 1.10(c).

CONCLUSION

For the reasons set forth above, the application is **ABANDONED**.

The NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 (Form PCT/DO/EO/905) mailed 10 July 2008 is <u>VACATED</u>.

Applicants may wish to consider filing a petition under 37 CFR 1.10(c).

Any further correspondence with respect to this matter may be filed electronically via EFS-Web or if mailed should be addressed to Mail Stop PCT, Commissioner for Patents, Office of PCT Legal Administration, P.O. Box 1450, Alexandria, Virginia 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.

This application is being forwarded to the National Stage Processing Branch of the Office of PCT Operations for preparation and mailing of a NOTIFICATION OF ABANDONMENT.

/Daniel Stemmer/

Daniel Stemmer
Legal Examiner
PCT Legal Affairs
Office of Patent Cooperation Treaty
    Legal Administration
Telephone: (571) 272-3301
Facsimile: (571) 273-0459

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Colloca, *et al.*
Serial No.:	10/587,389 - Case No.: ITR0048YP
Filed:	July 24, 2006
For:	CHIMPANZEE ADENOVIRUS VACCINE CARRIERS

Art Unit:

Examiner:

RECEIVED

Mail Stop PCT
Commissioner for Patents
Office of PCT Legal Administration
P.O. Box 1450
Alexandria, VA 22313-1450

FEB 02 2009

PCT LEGAL
ADMINISTRATION

DECLARATION OF LINDA M. ZEHRER

Sir:

I, Linda M. Zehrer, hereby declare the following:

1.   I have been employed by Merck & Co., Inc. beginning in 1987 and currently hold the title of Staff Associate I in the Legal Administration Department.

2.   In July 2006, my position title was Docket Specialist/Team Leader. At that time, my job responsibilities at Merck included receiving correspondence from attorneys in the Merck Patent Department to be sent to the US Patent & Trademark Office (USPTO) through the Express Mail "Post Office to Addressee" service of the US Postal Service (USPS).

3.   It is Applicants' practice for a Docket Specialist to deposit all correspondence to be sent to the USPTO via the Express Mail "Post Office to Addressee" service of the USPS ("Express Mail") directly with an employee of the USPS. It is further Applicants practice for the Docket Specialist who is responsible for delivering all Express Mail correspondence to an employee of the USPS to sign all "Express Mail Certificates," which are stamped on the documents to be filed via Express Mail. The USPS employee who receives the Express Mail

correspondence from that day then writes the "date in" and "time in" on the Express Mail receipt(s) and returns the filled-in "Customer copy" of the receipt(s) to the Docket Specialist. The Docket Specialist then reviews the Customer Copies of the Express Mail receipt(s) for that day to confirm that the USPS employee wrote the correct date under "date-in" on the Express Mail receipt.

4.   It is also Applicants practice to include a postcard in the Express Mail envelope which lists all of the documents included therein. Besides a list of documents, the postcard indicates, *inter alia*, Applicants' docket number, the date of mailing, the Express Mail number, and the Title of the Invention. Under "date" on the postcard, it is Applicants' practice to write the date that the correspondence is being personally delivered to an employee of the USPS. Once the postcard is received by an employee of the USPTO, it is stamped with the date and returned to Applicants.

5.   On July 24, 2006, I was the Docket Specialist assigned to deliver Applicants' Express Mail correspondence directly to an employee of the USPS. I received the correspondence from Applicants related to Application No. 10/587,389 and signed the "Express Mail Certificates" certifying that I was depositing the correspondence with the USPS as Express Mail "Post Office top Addressee" in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. I then personally delivered the correspondence to an employee of the USPS.

6.   Attached hereto as "Exhibit A-1" is a copy of the Transmittal Letter to the US Designated/Elected Office Concerning a Filing under 35 U.S.C. §371 for the above-referenced application. The Transmittal Letter contains an Express Mail Certificate for Express Mail No. EV321988999US that certifies that I received this correspondence and deposited it with the USPS as Express Mail "Post Office to Addressee" on July 24, 2006, in an envelope marked Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

7.   Attached hereto as "Exhibit B-1" is a copy of the Sequence Requirement Statement for the above-referenced application. The Sequence Requirement Statement contains an Express Mail Certificate for Express Mail No. EV321988999US that certifies that I received this correspondence and deposited it with the USPS as Express Mail "Post Office to Addressee" on July 24, 2006, in an envelope marked Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

8.   Attached hereto as "Exhibit C-1" is a copy of the Information Disclosure Statement under 37 C.F.R. 1.97 for the above-referenced application. The Information Disclosure Statement contains an Express Mail Certificate for Express Mail No. EV321988999US that certifies that I received this correspondence and deposited it with the USPS as Express Mail "Post Office to Addressee" on July 24, 2006, in an envelope marked Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

9.   Attached hereto as "Exhibit D-1" is a photocopy of the "Customer Copy" of the Express Mail receipt for Express Mail No. EV321988999US. The receipt shows the "Date in" as July 24, 2006. If the USPS employee who received Applicant's correspondence for delivery via Express Mail on July 24, 2006 had written an incorrect date on the Express Mail receipt, the Docket Specialist reviewing the "Customer Copy" of the Express Mail receipt would have brought the error to the attention of the attorney responsible for the application. In this case, I reviewed the "date-in" on the Express Mail receipt and confirmed that it correctly indicated July 24, 2006.

10.   Attached hereto as "Exhibit E-1" is a copy of the postcard included in the Express Mail envelope for Application No. 10/587,389 and returned to Applicants by the USPTO. The postcard indicates that the Express Mail envelope for Express Mail No. EV321988999US included, *inter alia*, the transmittal and Declaration and Power of Attorney for the application at issue. The date indicated by Applicants on the postcard is July 24, 2006. The date stamped "received PCT/PTO" is July 25, 2006.

11.   I hereby declare that all statements made herein of my own knowledge are true and that all statements made of information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

By _____
Linda M. Zehrer

Date: _____

Exhibit A-1

Transmittal Letter to the US Designated/Elected Office Concerning a Filing Under 35 U.S.C. § 371

U. S. PATENT AND TRADEMARK OFFICE U.S. DEPARTMENT OF COMMERCE	ATTORNEY'S DOCKET NUMBER ITR0048YP
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO. PCT/EP2005/000558	INTERNATIONAL FILING DATE 1/18/2005	PRIORITY DATE CLAIMED January 23, 2004

TITLE OF INVENTION

CHIPANZEE ADENOVIRUS VACCINE CARRIERS

APPLICANT(S) FOR DO/EO/US   JUl 2 -, 7Ủн

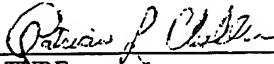Stefano Colloca, Alfredo Nicosio, Elisabetta Sproreno, Agostino Cirillo, Bruno Bruni Ercole, Annalisa Meola

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.

2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.

3. ☐ This is an express request to begin national examination procedures [35 U.S.C. 371(f)]. The submission must include items (5), (6), (9) and (21) indicated below.

4. ☐ The US has been elected (PCT Article 31).

5. ☒ A copy of the International Application as filed [35 U.S.C. 371(c)(2)]
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).

6. ☐ An English language translation of the International Application as filed [35 U.S.C. 371(c)(2)].
   a. ☐ is attached hereto
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).

7. ☐ Amendments to the claims of the International Application under PCT Article 19 [35 U.S.C. 371(c)(3)].
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.

8. ☐ An English language translation of the amendments to the claims under PCT Article 19 [35 U.S.C. 371(c)(3)].

9. ☒ An oath or declaration of the inventor(s) [35 U.S.C. 371(c)(4)].

10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 [35 U.S.C. 371(c)(5)].

Items 11 to 20 below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. ☐ A preliminary amendment.

14. ☐ An Application Data Sheet under 37 CFR 1.76.

15. ☐ A substitute specification.

16. ☐ A power of attorney and/or change of address letter.

17. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.

18. ☐ A second copy of the published Internᴧtional Application under 35 U.S.C.154(d)(4).

19. ☐ A second copy of the English language translation of the international applicatic� under 35 U.S.C.154(d)(4).

20. ☐ Other items or information:

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO. PCT/EP2005/000558	ATTORNEY'S DOCKET NUMBER ITR0048YP

The following fees are submitted:	CALCULATIONS	PTO USE ONLY

		CALCULATIONS	PTO USE ONLY
21. [X] Basic national fee...$300		$300.00	

22. [X] Examination fee (37 CFR 1.492(c))
If the written opinion prepared by ISA/US or the international preliminary examination report
prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).................................$0
All other situations...$200

23. [X] Search fee (37 CFR 1.492(b))
If the written opinion of the ISA/US or the international preliminary examination report prepared by
IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).......................................$0
Search fee [37 CFR 1.445(a)(2)] has been paid on the international application to the USPTO as an
International Searching Authority..$100
International Search Report prepared by an ISA other than the US and provided to the Office or
previously communicated to the US by the IB $400
All other situations...$500

TOTAL OF 21, 22 and 23=	$300.00	

[ ] Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is $250 for each additional 50 sheets of paper or fraction thereof.

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
162 - 100 =	62 /50	1.24 = 2	X $250.00	$500.00	

Surcharge of **$130.00** for furnishing the oath or declaration later than 30 months from the earliest claimed priority date [37 CFR 1.492(e)].

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	42 - 20 =	22	X $50.00	$1,100.00	
Independent Claims	13 - 3 =	10	X $200.00	$2,000.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $360.00		
TOTAL OF ABOVE CALCULATIONS (SUBTOTAL)			=	$3,900.00	

Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).	+		
TOTAL NATIONAL FEE	=	$3,900.00	

Fee for recording the enclosed assignment [37 CFR 1.21(h)]. The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31).**$40.00** per property.	+		
TOTAL FEES ENCLOSED	=	$3,900.00	

	Amount to be refunded:	
	Amount to be charged:	

a. [ ] A check in the amount of $ _____ to cover the above fees is enclosed.

b. [X] Please charge my Deposit Account No. 13-2755 in the amount of $3,900.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to the Deposit Account No. 13-2755. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive [37 CFR 1.137(a) or (b)] must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer No. 000210

MERCK & CO., INC.
Patent Department, RY60-30
P.O. Box 2000
126 East Lincoln Avenue
Rahway, New Jersey 07065-0970

SIGNATURE

Patricia L. Chisholm
NAME

DATE: July 24, 2006

PHONE #:   (732) 594-5738

45,822
REGISTRATION NUMBER

Computer generated form "TransLetter (DO-EO-US)" (PCT Folder), Merck & Co., Inc., 12/2/2005

Page 1A of TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

Attorney Docket No.:   ITR0048YP

International Appln No.:   PCT/EP2005/000558

International Filing Date: JANUARY 18, 2005

Priority Date: JANUARY 23, 2004

Title: CHIMPANZEE ADENOVIRUS VACCINE CARRIERS

Inventors: Stefano Colloca, Alfredo Nicosio, Elisabetta Sproreno, Agostino Cirillo, Bruno Bruni Ercole, Annalisa Meola

---

EXPRESS MAIL CERTIFICATE

DATE OF DEPOSIT _July 24, 2006_

EXPRESS MAIL NO. EV321988999US

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL "POST OFFICE TO ADDRESSEE" ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450.

MAILED BY _Linda Zehrer_ DATE _July 24, 2006_

Exhibit B-1

Sequence Requirement Statement

<u>PATENT</u>

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Colloca, Stefano, *et al.*		
Serial No.:	To Be Assigned	Case No.: ITR0048YP	Art Unit: To be assigned
Filed	On Even Date Herewith		Examiner: To be assigned
For:	CHIMPANZEE ADENOVIRUS VACCINE CARRIERS		

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

JUL 2 4 2006

<u>SEQUENCE REQUIREMENT STATEMENT</u>

Sir:

I hereby state that the contents of the paper and computer readable copies of the enclosed Sequence Listing, submitted in accordance with 37 C.F.R. § 1.821(c) and (e), respectively, are the same.

Respectfully submitted,

By _~Patricia L. Chisholm~_
Patricia L. Chisholm
Reg. No. 45,822
Attorney for Applicants

Merck & Co., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907
(732) 594-5738

Date: _July 24, 2006_

Exhibit C-1

Information Disclosure Statement
Under 37 C.F.R. 197

EXHIBIT C-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stefano Colloca, Alfredo Nicosio, Elisabetta
Sproeno, Agostino Cirillo, Bruno Bruni Ercole,
Annalisa Meola

Serial No.   To be assigned

Filed: Herewith

For: CHIMPANZEE ADENOVIRUS VACCINE CARRIERS

Art Unit: <u>To be assigned</u>

Examiner: <u>To be assigned</u>

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

JUL 2 4 2006

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

EXPRESS MAIL CERTIFICATE
DATE OF DEPOSIT _July 24, 2006_
EXPRESS MAIL NO. _EV331922981US_
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS
BEING DEPOSITED WITH THE UNITED STATES POSTAL
SERVICE AS EXPRESS MAIL "POST OFFICE TO ADDRESSEE"
ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO
COMMISSIONER FOR PATENTS, P.O. BOX 1450,
ALEXANDRIA, VIRGINIA 22313-1450.
MAILED BY _Linda Zeller_
DATE _July 24, 2006_

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:
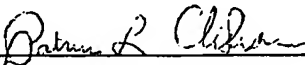
	RELATED APPLICATION	
U. S. SERIAL NUMBER	**FILING DATE**	**MERCK CASE**

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

[✓] the attached information is filed within three months of the filing date of the captioned case.

[ ] the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.

[ ] the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

[ ] the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).

[ ] each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.

[ ] each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*

[ ] no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: Patricia L. Chisholm

<u>Attorney</u>   For Applicant(s)

Reg. No. <u>45,822</u>
MERCK & CO., INC.
Patent Dept., RY60-30
P.O. Box 2000
Rahway, N.J. 07065-0907
(732)594-<u>5738</u>
Date: _July 24, 2006_

Exhibit D-1

"Customer Copy" of the Express Mail Receipt

EXHIBIT D-1

EV 321988999 US

EXPRESS MAIL
UNITED STATES POSTAL SERVICE®

Post Office To Addressee

ORIGIN (POSTAL USE ONLY)		
PO ZIP Code 07067	Day of Delivery ☑ Next ☐ Second	Flat Rate Envelope ☐
Date In 7 21 06 Mo. Day Year	☑ 12 Noon ☐ 3 PM	Postage $ 44 10
Time In 6 50 ☐ AM ☑ PM	Military ☐ 2nd Day ☐ 3rd Day	Return Receipt Fee
Weight 12 lbs. 5 ozs.	Int'l Alpha Country Code	COD Fee / Insurance Fee
No Delivery ☐ Weekend ☐ Holiday	Acceptance Clerk Initials	Total Postage & Fees $ 44 10

DELIVERY (POSTAL USE ONLY)		
Delivery Attempt Mo. Day	Time ☐ AM ☐ PM	Employee Signature
Delivery Attempt Mo. Day	Time ☐ AM ☐ PM	Employee Signature
Delivery Date Mo. Day	Time ☐ AM ☐ PM	Employee Signature

☐ WAIVER OF SIGNATURE (Domestic Only) Additional merchandise insurance is void if waiver of signature is requested. I wish delivery to be made without obtaining signature of addressee or addressee's agent (if delivery employee judges that article can be left in secure location) and I authorize that delivery employee's signature constitutes valid proof of delivery.
NO DELIVERY ☐ Weekend ☐ Holiday
Customer Signature

CUSTOMER USE ONLY

METHOD OF PAYMENT:
Express Mail Corporate Acct. No. **X070505**

Federal Agency Acct. No. or Postal Service Acct. No.

FROM: (PLEASE PRINT)   PHONE (732) 594 5738

```
MERCK & CO., INC.
PATENT DEPARTMENT    RY60-30
PO BOX 2000
RAHWAY                NJ 07065-0900
```
Patricia L. Chisholm

ITRC048YP (US National)

TO: (PLEASE PRINT)   PHONE ( )

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MAIL STOP
COMMISSIONER FOR PATENTS
PO BOX 1450
ALEXANDRIA          VA 22313-1450
```

PRESS HARD.
You are making 3 copies.   **FOR PICKUP OR TRACKING CALL 1-800-222-1811 www.usps.com**   EMS

Exhibit E-1

Postcard

EXHIBIT E-1

PLC

THE PATENT & TRADEMARK OFFICE ACKNOWLEDGES, AND HAS STAMPED HEREON, THE DATE OF THE RECEIPT AND THE ASSIGNED SERIAL NUMBER OF THE FOLLOWING PATENT APPLICATION:

ITR0048YP

CASE NUMBER	DATE	ATTORNEY	EXPRESS MAIL ☒
ITR0048YP	July 24, 2006	Patricia L Chisholm	EV.321988999145

IAP6 Rec'd PCT/PTO 25 JUL 2006

TITLE			
CHIMPANZEE ADENOVIRUS VACCINE CARRIERS			

INVENTORS Stefano Colloca, Alfredo Nicosio, Elisabetta Sporeno, Agostino Cirillo, Bruno Bruni Ercole, Annalisa Meola

NO. OF PAGES	NO. OF CLAIMS	PAGES OF DRAWING
—	42 claims	—

10/587389

JUL 25 2006 — PATENT & TRADEMARK OFFICE — IAP27

DECLARATIONS Transmittal, IDS + 22 references, Sequence Statement, Sequence disk, Sequence Paper Copy (193pgs)	ACCOUNT CHARGED 13 - 2755 $3,900.00

F1071.3 REV.9/93 Declaration and Power of Attorney